K100747

APR 14 2010

510(k) Summary	
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Date Prepared:	April 14, 2010
Trade Name:	Contrex Plus Low Control Solution
Classification:	Quality control material (assayed and unassayed), 21 CFR 862.1660, Class I (reserved).
Product Code:	JJX
Predicate Device:	Contrex Plus Level 1 and Level 2 Control Solutions
Device Description:	Control solution containing D-glucose as its reactive component for use as a quality control material for blood glucose monitoring systems.
Intended Use:	The purpose of the control solution test is to validate the performance of the GlucoSure STAR & GlucoTRACK Blood Glucose Monitoring Systems using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.
Comparison of Technological Characteristics:	The modified Contrex Plus Control Solution (Contrex Plus Low Control Solution) is identical to the predicate in so far as it also contains D-Glucose as the reactive ingredient and contains the same non-reactive ingredients (including buffers, stabilizer and preservative). The glucose range for the modified, Low Control Solution is 40-70 mg/dL; whereas, the ranges for the predicate Level 1 and Level 2 control solutions are 87-131 mg/dL and 186-280 mg/dL, respectively.

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Functional and Safety Testing:	Control solution qualification and stability testing was conducted and all results met specifications. Control solution qualification was conducted on one lot of control solution by range testing 80 test strips over 10 days. All results fell within the assigned control solution range. Control solution stability verification was conducted in a Use Life study (open vial and un-opened vial) and in a Shelf Life study. Use Life testing was done on 5 meters and one lot of test strips to support the claim of a 3-month open bottle use life. Three (3) lots of low control solution were tested. Eight (8) bottles were tested for each of the 3 lots. For each lot of control solution, a) 4 bottles were used for repeated testing in which they were opened every other day to express a drop of control solution and then tested on a test strip on Day 0 and months 1, 2 and 3 (open bottle testing) and b) 4 bottles were opened once for one-time testing on Days 0 and months 1, 2, and 3 (un-opened vial testing). All test strip results were within the assigned control solution range. Shelf Life testing was done on three (3) lots of low control solution stored at 30°C. Two lots of test strips and ten (10) meters were used. For each of the 3 lots of control solution, 10 test strips were tested at each test point. The test points occurred at weeks 0, 2, 5, 8, 13, 26, 39, 52, 78, 104, and 108. The claimed shelf life period for the control solution is 2 years (104 weeks). All test values were within the assigned control range.
Conclusion:	Contrex Plus Low Control Solution has the same formulation as the predicate other than using a lower glucose level and therefore presents at least as good safety as the predicate. Qualification testing shows that Contrex Plus Low Control Solution is effective as a control solution and performs at least as well as the predicate, as shown by testing were all results fell within the assigned control solution range. Use Life and Shelf Life testing show that the Contrex Plus Low Control Solution performs properly during its claimed use life and shelf life periods. These results from testing show that the Contrex Plus Low Control Solution is safe, effective, and performs at least as well as the predicate device. We conclude that the Contrex Plus Low Control Solution is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Apex BioTechnology Corp.
c/o Mr. Thomas Y.S. Shen
Regulatory Affairs Specialist
No. 7 Li-Hsin Road V, Hsinchu Science Park
Hsinchu, China (Taiwan) 30078

APR 14 2010

Re: k100747
Trade Name: Contrex Plus Low Control Solution
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: March 11, 2010
Received: March 16, 2010

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k100747

Device Name: Contrex Plus Low Control Solution

Indications for Use:

The purpose of the control solution test is to validate the performance of the GlucoSure STAR & GlucoTRACK Blood Glucose Monitoring Systems using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k): k100747